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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/754,362

01/08/2004

James Weldon

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

MASHACK, MARK F

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/754,362	Applicant(s) WELDON ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 4/8/2009. Claims 1-3, 5-16, and 19-20 are pending.

Response to Arguments

1. Applicant's arguments filed 4/8/2009 have been fully considered but they are not persuasive.
2. Applicant argues regarding the combination of **Strecker** and **Hlavka** that "one of ordinary skill in the art would not be motivated to incur signification additional mechanical operational complexity in order to obtain a result which **Strecker** obtains with a single securing means". Examiner respectfully disagrees. Examiner asserts that one of ordinary skill in the art would appreciate the desirability of an *improved* securement and fixation of an implant to a vascular wall even if it requires increased mechanical complexity. Examiner asserts that the fixation component taught by **Hlavka** is an improvement over the fixation component disclosed by **Strecker**.
3. Applicant argues "**Moss** does not appear to provide a longitudinal slot extending a length of the delivery channel... for the simple reason that at no time are the first and second fixation members of the fixation component in question both contained within the delivery member of **Moss**". Examiner contends that this a moot point. Examiner contends that **Moss** merely teaches of providing a slot in a delivery system to accommodate a suture that connects two fixation members. Examiner contends that this is an obvious modification to the system disclosed by **Strecker** in view of **Hlavka** to accommodate the suture without damaging it.

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4. Applicant argues that "the balloon catheter **210** appears to be incapable of providing the restraint which the Examiner proposes". Applicant goes further by questioning the inner sheath and releasable fixation member proposed by the examiner. First of all, Applicant misconstrues the Examiner's motivation. The combination of the inner sheath and releasable fixation member would provide the restraint. Element **210** of **Miller** can be considered an "inner sheath" because of the obvious modification of a guide wire lumen. Element **235** of **Miller** can be considered "a releasable fixation member" because it fixes and restrains the vascular graft to the distal end of the inner sheath.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. **Claims 1-3, 5-9,16, and 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Strecker (US 6,416,522)** in view of **Hlavka et al. (US 2004/0172046)** and **Moss (US 5,085,661)**.

Strecker discloses the following:

Regarding Claim 1, 16, and 19-20, a fixation system for fixing an implantable device in a body cavity, comprising: an implantable device (80, 87); a plurality of resilient delivery members movable between a generally longitudinal delivery position and a radially expanded deployment position (93), the delivery members defining a delivery channel therein with a distal opening, each delivery member having a distal end formed with a blunt profile adapted to engage the implantable device (Fig 12); a fixation component slidably disposed in each of the delivery channels (95); and a pusher slidably disposed in each of the delivery channels to push the fixation component in each delivery channel (98).

Regarding Claim 2, the fixation system of claim 1 and further comprising: a delivery sheath slidable over the plurality of resilient delivery members (89).

Regarding Claim 3, the fixation system of claim 1 wherein the delivery members define the delivery channel as a closed lumen therein with the distal opening (Fig 12).

Regarding Claim 5, the fixation system of claim 1 wherein the delivery members, when in the deployed position, urge the implantable device against a wall of the body cavity (Fig 13).

Regarding Claim 6, the fixation system of claim 5 wherein the first fixation member is disposed to pierce the implantable device and a wall of the body cavity when advanced from the delivery channel by the pusher (Fig 13).

Regarding Claim 7, the fixation system of claim 6 wherein the first fixation member has a sharpened end for piercing the implantable device and body cavity wall (95).

Regarding Claim 8, the fixation system of claim 6 wherein the first and second fixation members are arranged in a generally longitudinally aligned orientation when in the delivery channel (Fig 14).

Regarding Claim 9, the fixation system of claim 8 wherein one of the first and second fixation members are releasably connected to the pusher (Fig 12).

Strecker discloses in a separate embodiment the tab and slot which provides a disconnectable connection between the fixation component and the pusher (Figure 15 Items 103 and 107). The Examiner also notes that tab and slot configurations are well known in drivers, the most common being a screw driver. Essentially, the pusher is guiding the anchor into place. A tab and slot configuration is old and well known to aid in the control of the anchor by the pusher. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's pusher and anchor to include a tab and a slot as is known in the art. Such a modification aids in controlling the anchor with the pusher.

Strecker does not disclose each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second

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fixation members. **Strecker** also does not disclose each of the delivery members having a longitudinal slot communicating with an exterior of the delivery member and extending a length of the delivery channel, wherein the tether passes through the longitudinal slot of the delivery members.

Hlavka teaches each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members (Fig 10a Items 904 and 905). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation system to include Hlavka's fixation member and tether. Such a modification would allow the two members to be pulled against one another with the tissue and/or graft between them, thus securing the graft to the tissue.

Moss teaches of a similar fastener delivery system to **Strecker** comprising a pusher **6**, first **38** and second **38'** fixation components attached by a suture **46**, and a delivery member **6** comprising a longitudinal slot. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Moss**, it would have been obvious to one of ordinary skill in the art at the time of the inventions to modify the delivery member of **Strecker** with a longitudinal slot. Doing so would allow for the tether fixation devices to be used with a pusher delivery system.

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8. **Claims 10-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Strecker (US 6,416,522)** in view of **Miller (WO 02/17797)**, **Hlavka et al. (US 2004/0172046)**, and **Moss (US 5,085,661)**.

Strecker discloses the invention substantially as claimed as stated above.

Strecker discloses in a separate embodiment the tab and slot which provides a disconnectable connection between the fixation component and the pusher (Figure 15 Items 103 and 107). The Examiner also notes that tab and slot configurations are well known in drivers, the most common being a screw driver. Essentially, the pusher is guiding the anchor into place. A tab and slot configuration is old and well known to aid in the control of the anchor by the pusher. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's pusher and anchor to include a tab and a slot as is known in the art. Such a modification aids in controlling the anchor with the pusher.

Strecker does not disclose an inner sheath, a releasable fixation member, and an expandable member at the distal end of the sheath.

Miller teaches an inner sheath, the plurality of delivery members being arranged generally radially about the inner sheath (Fig 12 Item 210), a releasable fixation member releasably fixing the vascular graft to a distal end of the inner sheath (Fig 16 Item 235), an expandable member expandable from a contracted position closely proximate an exterior of the delivery sheath to an expanded position urging the vascular graft against the wall of the body cavity (Fig 15 Item 210), the expandable member is positioned at a distal end of the delivery sheath (Fig 10 Item 210), and the expandable

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member has a distal end thereof shaped in the expanded position to conform to a shape of the delivery members in the deployment position (210). The Examiner notes that the Applicant is suggesting the inner sheath is non-obvious in view of Miller. The Examiner disagrees. At the very least, it is well known to have guide wires in these systems. The guide wire would have its own lumen enclosing the guide wire to keep it stable and in position. This would be a sheathed guide wire. The device would encircle the guide wire placing the delivery members around the inner sheath. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation system to include Miller's inner sheath and expandable member. Such a modification would restrain the delivery members until deployment, fix the graft until deployment preventing undesirable release, and a balloon to ensure full expansion of the graft.

Strecker does not disclose each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members.

Hlavka teaches each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members (Fig 10a Items 904 and 905). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation system to include Hlavka's fixation member and tether. Such a modification would allow the two members to be pulled against one another with the tissue and/or graft between them, thus securing the graft to the tissue.

Strecker also does not disclose each of the delivery members having a longitudinal slot communicating with an exterior of the delivery member and extending a length of the delivery channel, wherein the tether passes through the longitudinal slot of the delivery members.

Moss teaches of a similar fastener delivery system to **Strecker** comprising a pusher **6**, first **38** and second **38'** fixation components attached by a suture **46**, and a delivery member **6** comprising a longitudinal slot. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Moss**, it would have been obvious to one of ordinary skill in the art at the time of the inventions to modify the delivery member of **Strecker** with a longitudinal slot. Doing so would allow for the tether fixation devices to be used with a pusher delivery system.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

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/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773